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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,844	03/17/2000	Timothy J. Barberich	4821-334-999	3697

20582 7590 05/05/2004

JONES DAY
51 Louisiana Aveue, N.W
WASHINGTON, DC 20001-2113

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Communication Re: Appeal	**Application No.** 09/527,844	**Applicant(s)** BARBERICH ET AL.
	Examiner Shahnam Sharareh	**Art Unit** 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ The Notice of Appeal filed on *12/30/2003,2/17/2004* is not acceptable because:

   (a) ☐ it was not timely filed.

   (b) ☒ the statutory fee for filing the appeal was not submitted. See 37 CFR 1.17(b).

   (c) ☐ the appeal fee received on _____ was not timely filed.

   (d) ☒ the submitted fee of $*110.00* is insufficient. The appeal fee required by 37 CFR 1.17(b) is $*420.00*.

   (e) ☐ the appeal is not in compliance with 37 CFR 1.191 in that there is no record of a second or a final rejection in this application.

   (f) ☐ a Notice of Allowability, PTO-37, was mailed by the Office on _____.

2. ☒ The appeal brief filed on *2/11/ and 2/17/2004* is NOT acceptable for the reason(s) indicated below:

   (a) ☐ the brief and/or brief fee is untimely. See 37 CFR 1.192.

   (b) ☐ the statutory fee for filing the brief has not been submitted. See 37 CFR 1.17(c).

   (c) ☐ the submitted brief fee of $_ is insufficient. The brief fee required by 37 CFR 1.17(c) is $_.

The appeal in this application will be dismissed unless corrective action is taken to timely submit the brief and requisite fee. Extensions of time may be obtained under 37 CFR 1.136(a).

3. ☐ The appeal in this application is DISMISSED because:

   (a) ☐ the statutory fee for filing the brief as required under 37 CFR 1.17(c) was not timely submitted and the period for obtaining an extension of time to file the brief under 37 CFR 1.136 has expired.

   (b) ☐ the brief was not timely filed and the period for obtaining an extension of time to file the brief under 37 CFR 1.136 has expired.

   (c) ☐ Request for Continued Examination (RCE) under 37 CFR 1.114 was filed on _____.

   (d) ☐ other: _____

4. ☐ Because of the dismissal of the appeal, this application:

   (a) ☐ is abandoned because there are no allowed claims.

   (b) ☐ is before the examiner for final disposition because it contains allowed claims. Prosecution on the merits remains CLOSED.

   (c) ☐ is before the examiner for consideration of the submission and prosecution has been reopened pursuant to 37 CFR 1.114.

RUSSELL TRAVERS
PRIMARY EXAMINER

Defective Appeal Brief

The Brief filed on December 30, 2003 is defective for the following reasons:

1. The brief includes a statement that claims 1-4, 6-15; claim 5; claims 50-51 and claims 52-53 do not stand or fall together, but fails to present reasons in support thereof as required under 37 CFR 1.192(c)(7). MPEP § 1206.
2. No amendment can be made as a matter of right in appealed cases. In this case, the claim amendments presented on the Brief is not deemed to place the rejected claims in better form for consideration on appeal.
3. The appeal brief filed on December 30, 2003 is unacceptable because the fee required under 37 CFR 1.17 (a), (c) was not timely filed for the following reasons:
    - The final action was mailed on June 18, 2003.
    - Applicant purchased one-month extension and filed a Notice of Appeal on September 2003, therefore, the Brief should have been filed by December 18, 2003.
    - The Brief was filed on December 30, 2003 with authorizing charges for one-month extension and the filing fee for the Brief to effectively move the filing deadline to January 18, 2004. However, the account did not have sufficient funds to maintain the pendency of the case at that time. Thus, the Application was constructively out of time.
    - On February 13th and 17th, the account was cleared for the one-month extension and the filing fee for the Brief due on December 30, 2003.

- Therefore, under 37 CFR 1.17(a) and (c), Appellant must pay an additional month to obtain appropriate extension of time until February 18, 2004 when all submissions are properly filed.

This application will become abandoned unless appellant obtains an extension of time under 37 CFR 1.136(a) and files the required appeal brief fee. The date on which the appeal brief, the fee for filing the appeal brief, the petition under 37 CFR 1.136(a), and the petition fee under 37 CFR 1.17(a) are filed will be the date of the reply and also the date for determining the period of extension and the corresponding amount of the fee. In no case may an appellant obtain an extension for more than FIVE MONTHS under 37 CFR 1.136(a), beyond the TWO MONTH period for filing the appeal brief.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ss

RUSSELL TRAVERS
PRIMARY EXAMINER

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2 more month

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09/527,844	03/17/2000	Timothy J. Barberich	4821-334-999	3697

20582 7590 06/18/2003

PENNIE & EDMONDS LLP
1667 K STREET NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER
BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
1617	19

DATE MAILED: 06/18/2003

6/18/2003

1 month extension

NOV

Please find below and/or attached an Office communication concerning this application or proceeding.

6/18
9/18 — 1 month
10/18 — Notice of Appeal
2 month
Dec/18 — 3 months
Feb 24

9/18
(month)
0 — oct
1 monorem
2 months free
~~Dec 30th~~
2

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/527,844	BARBERICH ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 50-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 50-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's response to the office action of November 5, 2002, and amendment submitted April 4, 2003 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. abstract (AN 1997: 593623 CAPLUS).

Davis et al. abstract discloses ziprasidone as an antipsychotic drug having high affinity for serotonin 5-HT2 and dopamine D2 receptors. Davis et al. further discloses that clinical trials have shown ziprasidone to be effective in treating depression associated with schizophrenia, and in reducing anxiety in patients about to undergo dental surgery, see abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. abstract (AN 1997: 593623 CAPLUS) in view of Lowe et al. (USPN 4,831,031), Allen et al. (USPN 5,312,925) and Parkash et al.

Davis et al. abstract discloses ziprasidone as an antipsychotic drug having high affinity for serotonin 5-HT2 and dopamine D2 receptors. Davis et al. further discloses that clinical trials have shown ziprasidone to be effective in treating depression associated with schizophrenia, and in reducing anxiety in patients about to undergo dental surgery, see abstract.

Davis et al. does not specifically teach metabolites of ziprasidone, amounts (i.e., dosage), routes of administration.

Lowe et al. (USPN 4,831,031) teaches that aryl piperazinyl (C2-C4) alkylene heterocyclic compounds (including ziprasidone) and their pharmaceutically acceptable salts, known neuroleptic agents, can be administered orally, in form of tablets or capsules or parentrally, see col. 3, line 54-col.4 line 33. Lowe et al also teaches that a daily dosage range is from 5 to 500 mg, see in particular col. 4, lines 3-33, see also claims 1-9.

Allen et al. (USPN 5,312,925) specifically teaches the employment of ziprasidone hydrochloride as a neuroleptic agent.

Parkash teaches the affinity of the sulfone and sulfoxide metabolites of ziprasidone for 5-HT2 and D2 receptors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ ziprasidone or any of its known salts or metabolites in a method of treating neuroleptic disorders.

One of ordinary skill in the art would have been motivated to employ ziprasidone or any of its known salts or metabolites in a method of treating neuroleptic disorders, because ziprasidone in general and ziprasidone hydrochloride are known neuroleptic agents employed in treating anxiety, depression associated with schizophrenia and situational anxiety (i.e., anxiety prior to dental surgery). Employment of different salts and metabolites of a known active is within the skill of the artisan and therefore obvious.

Response to Arguments

Applicant's arguments filed April 4, 2003 have been fully considered but they are not persuasive. In response to the rejection under 35 USC 102, applicant argues that the instant claims are drawn to a method of employing ziprasidone metabolites and not ziprasidone itself in treating disorders ameliorated by the inhibition of seratonin reuptake and/or dopamine reuptake. As set forth in the previous office action, note that ziprasidone converts to its metabolites *in vivo*. Therefore the administration of ziprasidone results in its conversion to metabolites thereof. Consequently, the administration of ziprasidone necessarily and inherently results in its administration/conversion to ziprasidone metabolites *in vivo*. Therefore each and every element of the claim is indeed met. Applicant then argues that the disclosure of dosage forms in the specification presupposes the existence of a ziprasidone metabolite prior to its administration to a patient. Note that none of the claims rejected under 35 USC 102 recites a dosage form and arguments as to unclaimed limitations are moot. In response to applicant's argument that the

references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., inclusion of the metabolites in the dosage forms) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant then argues that there is no motivation to combine the three prior art references used in the obviousness rejection. Applicant argues that none of the three references teaches the employment of ziprasidone metabolites. Note that all references teach the employment of ziprasidone itself and as argued herein above, the employment of the metabolites of ziprasidone would result in the same *in vivo* activity. Therefore following the court's ruling in *Zenith Laboratories Inc. v. Bristol-Myers Squibb Co.*, the Skilled Artisan would know that the compound Ziprasidone is not limited to "its pre-ingested form", 30 USPQ2d 1285, 1289. In the instant case the ziprasidone metabolites are employed to treat disorders ameliorated by the inhibition of seratonin reuptake and/or dopamine reuptake. Ziprasidone itself is known to be useful in treating these diseases via the same mechanisms, therefore it would have been obvious to employ the metabolites in lieu of ziprasidone in treating these same disorders. Applicant further argue and supply the Ereshefsky reference showing that the ziprasidone metabolites are inactive. Note the Parkash et al. reference in the 103 rejection herein above which teaches that ziprasidone sulfone and sulfoxide--though not as active as ziprasidone itself--nevertheless exhibit affinities for 5-HT2 and D2 receptors. Therefore at the very least the particular metabolites taught in Parkash et al. are not inactive.

Applicant then argues against the obviousness rejection, stating that in order for administration of ziprasidone metabolites to result in the same *in vivo* activity as the administration of ziprasidone itself, ziprasidone itself must be inactive. As shown herein above in the Parkash et al. reference, both ziprasidone and its metabolites are known to have affinities for 5-HT2 and D2 receptors, therefore they have the same activity.

Applicant finally argues that Examiner's reliance on Zenith is misplaced. It appears that the applicant argues that the court's reasoning cannot be applicable to the case at bar because Zenith was an infringement case and did not concern anticipation or obviousness. Note that although the case was based on an infringement suit, the court's reasoning is nevertheless applicable to the case at bar since one of the questions before the court was the relation between pre-ingested and ingested form of a drug.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
June 10, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER
6/14/03